SEP 27 2005

K051667

510(k) Summary

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter Address:**	MedicSense, Ltd. 14 Imber St. Kiriat Arie Petah Tikva, Israel 49511 www.medicsense.com
1. (b)	***Manufacturer Address:***	Indolor, Ltd. 429 Hamered St. POB 50114 Tel Aviv, Israel 61500
	Mfg. Phone:	972-3-510-8801
	Contact Person:	Uri Erez, Product Manager
	Date:	June 19, 2005
2.	***Device Name & Classification Name:***	Modified Easy-Ject Automatic Injector Device (also known as EZ-Ject) Syringe Needle Introducer, Class 2, Product Code 80KZH, 21 CFR 880.6920
3.	***Predicate Devices:***	Easy-Ject Automatic Injector Device K972383
4.	***Description:***	The Modified Easy-Ject Automatic Injector is a hand held device that performs automatic subcutaneous needle injection and retraction. The device incorporates a disk shaped cooling element that cools the skin prior to the needle injection.
5.	***Intended Use:***	The Modified Easy-Ject Automatic Injector Device is an automatic injection device with a cooling mechanism for injection and needle withdrawal.
6.	***Comparison of Technological Characteristics:***	With respect to technology, the Modified Easy-Ject Automatic Injector Device is substantially equivalent to its predicate device, the Easy-Ject. The major differences are the size, ergonomics, and the ability to operate with batteries. These modifications have not changed the safety or efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2005

Indolor, Limited
C/O Mr. George J. Hattub
Senior Staff Consultant
MedicSense, Limited
291 Hillside Avenue
Somerset, Massachusetts 02726

Re: K051667
Trade/Device Name: EZ-JECT
Regulation Number: 21 CFR 880.6920
Regulation Name: Syringe Needle Inducer
Regulatory Class: II
Product Code: KZH
Dated: June 19, 205
Received: July 8, 2005

Dear Mr. Hattub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

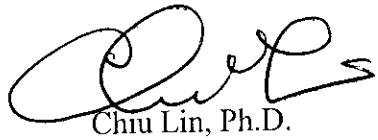
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051667

Device Name: Modified Easy-Ject Automatic Injector Device

Indications For Use: The Modified Easy-Ject Automatic Injector Device (also known as EZ-Ject) is an automatic injection device with a cooling mechanism for injection and needle withdrawal.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K051667

Revised 7-17-05